UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF JANUARY 2025

COMMISSION FILE NUMBER 001-39081

BioNTech SE
(Translation of registrant's name into English)

An der Goldgrube 12
D-55131 Mainz
Germany
+49 6131-9084-0
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F: Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

DOCUMENTS INCLUDED AS PART OF THIS FORM 6-K

On January 14, 2025, BioNTech SE outlined its 2025 strategic priorities at the 43rd annual J.P. Morgan Healthcare Conference. The press release and presentation are attached as Exhibits 99.1 and 99.2, respectively.

SIGNATURE

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioNTech SE

By: /s/ Jens Holstein
Name: Jens Holstein
Title: Chief Financial Officer

By: /s/ Dr. Sierk Poetting
Name: Dr. Sierk Poetting
Title: Chief Operating Officer

Date: January 14, 2025

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	BioNTech provides business and pipeline updates at 43rd annual J.P. Morgan Healthcare Conference
99.2	Presentation

BIONTECH

BioNTech provides business and pipeline updates at 43rd annual J.P. Morgan Healthcare Conference

- *Executing in oncology with investigational BNT327/PM8002 combinations and mRNA cancer immunotherapy candidates as pan-tumor treatment approaches*
- *BioNTech aims to develop BNT327/PM8002 as a next-generation immuno-oncology ("IO") backbone for the Company's combination strategy targeting a broad range of indications*
- *Progressing development of BNT327/PM8002 with initiation of global clinical trials with registrational potential in first-line small cell lung cancer ("SCLC") and non-small cell lung cancer ("NSCLC")*
- *Advancing BNT327/PM8002 combination strategy with initiation of a second antibody drug conjugate ("ADC") combination trial; additional ADC-combination trials planned to be initiated in 2025*
- *Progress in mRNA cancer immunotherapy portfolio with multiple randomized trial read-outs of personalized and off-the-shelf candidates expected in 2025 and 2026*

MAINZ, Germany, January 14, 2025 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company") today will present its 2025 strategic priorities and progress on the Company's pipeline of mRNA therapeutics, immunomodulators, and targeted therapies at the 43rd Annual J.P. Morgan Healthcare Conference in San Francisco, California.

"We aim to develop BioNTech into a global immunotherapy powerhouse with the potential to improve the standard of care with innovative oncology products and prophylactic vaccines against infectious diseases. In oncology, we are focused on addressing the full spectrum of solid tumors with investigational combination therapies in two pan-tumor technology pillars: our mRNA-based cancer immunotherapies for the early, adjuvant setting, and our differentiated anti-PD-L1/-VEGF-A bispecific antibody candidate BNT327/PM8002 for the treatment of advanced cancers. With our capabilities, we believe BioNTech is uniquely positioned to develop personalized, yet scalable cancer treatments based on mRNA," said **Prof. Ugur Sahin, M.D., Co-Founder and Chief Executive Officer of BioNTech**. "2025 is an important year, with data updates expected across both pillars and additional global clinical trial starts planned to generate evidence on our combination treatment concepts."

Prof. Ugur Sahin, M.D., will present strategic priorities and a pipeline update at the conference on Tuesday, January 14, 2025, at 6:00 p.m. CET/ 12:00 p.m. EST. A live webcast of the presentation will be available on the "Events & Presentations" page in the investor relations section on the Company's website. A replay of the webcast will be archived on the Company's website for 30 days following the conference.

Summary of selected pipeline updates

BNT327/ PM8002, an investigational bispecific antibody combining PD-L1 checkpoint inhibition with VEGF-A neutralization being developed in collaboration with Biotheus:

- In December 2024, BioNTech initiated a global randomized Phase 3 clinical trial (NCT06712355) evaluating BNT327/PM8002 plus chemotherapy compared to atezolizumab plus chemotherapy in first line extensive-stage small cell lung cancer ("ES-SCLC").
- In December 2024, BioNTech initiated a global randomized Phase 2/3 clinical trial (NCT06712316) evaluating BNT327/PM8002 plus chemotherapy compared to pembrolizumab and chemotherapy in first line NSCLC.
- A global randomized Phase 3 clinical trial evaluating BNT327/PM8002 in first line triple-negative breast cancer ("TNBC") is on track to start in 2025.

- Plan to initiate additional clinical trials exploring novel combinations of BNT327/PM8002 with ADCs BNT323/DB-1303 (trastuzumab pamirtecan), BNT324/DB-1311 and BNT326/YL202 in 2025.
- Plan to present first clinical data from the ongoing global Phase 1/2 expansion cohorts (NCT05438329) evaluating BNT327/PM8002 plus BNT325/DB-1305 in multiple solid tumors in 2025.
- Plan to present clinical data from the ongoing global Phase 2 dose optimization trials evaluating BNT327/PM8002 plus chemotherapy in advanced TNBC (NCT06449222) and first line SCLC (NCT06449209) in 2025.

Autogene cevumeran (BNT122/RO7198457), an investigational mRNA cancer immunotherapy based on an individualized neoantigen-specific immunotherapy ("iNeST") approach being developed in collaboration with Genentech Inc. ("Genentech"), a member of the Roche Group:
- In December 2024, the first patient was treated in a global randomized Phase 2 clinical trial (IMCODE004) (NCT06534983) evaluating autogene cevumeran in combination with nivolumab compared to nivolumab alone in high-risk muscle-invasive urothelial carcinoma ("MIUC").
- Interim data from an ongoing global randomized Phase 2 clinical trial (NCT04486378) evaluating autogene cevumeran compared to watchful waiting in adjuvant ctDNA+ stage II (high risk) / stage III colorectal cancer ("CRC") are anticipated in late 2025 or 2026.

BNT323/DB-1303 (trastuzumab pamirtecan), an investigational HER2-targeted ADC being developed in collaboration with Duality Biologics (Suzhou) Co. Ltd. ("DualityBio"):
- Plan to present clinical data from an ongoing Phase 1/2a trial (NCT05150691) evaluating BNT323/DB-1303 in HER2-expressing advanced endometrial cancer in 2025.
- Preparation of a potential Biologics License Application ("BLA") submission for BNT323/DB-1303 as a second line or subsequent therapy in HER2-expressing advanced endometrial cancer in 2025.
- Plan to initiate a global Phase 3 confirmatory clinical trial (NCT06340568) evaluating BNT323/DB-1303 in advanced endometrial cancer in 2025.

COVID-19 vaccine and other candidates
- For 2025, BioNTech and Pfizer Inc. ("Pfizer") expect largely stable vaccination rates and market share in the U.S. and revenue phasing similar to 2024, primarily concentrated in the back half of the year, with the distribution between Q3 and Q4 dependent on the timing of strain recommendation and approvals by regulatory agencies. Advanced purchase agreements remain in place outside of the U.S., including in the European Union.
- BioNTech and Pfizer continue to invest in the research and development of next-generation and combination COVID-19 vaccine candidates.

Upcoming Investor and Analyst Events
- Full Year and Fourth Quarter 2024 Financial Results: March 10, 2025
- Annual General Meeting: May 16, 2025

About BioNTech
Biopharmaceutical New Technologies (BioNTech) is a global next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. BioNTech exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor (CAR) T cells, several protein-based therapeutics, including bispecific immune checkpoint modulators, targeted cancer antibodies and antibody-drug conjugate (ADC) therapeutics, as well as small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse

oncology pipeline. BioNTech has established a broad set of relationships with multiple global and specialized pharmaceutical collaborators, including Biotheus, DualityBio, Fosun Pharma, Genentech, a member of the Roche Group, Genevant, Genmab, MediLink, OncoC4, Pfizer and Regeneron.

For more information, please visit www.BioNTech.com.

BioNTech Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: BioNTech's expected revenues related to sales of BioNTech's COVID-19 vaccine; the rate and degree of market acceptance of BioNTech's COVID-19 vaccine and, if approved, BioNTech's investigational medicines; expectations regarding regulatory recommendations to adapt vaccines to address new variants or sublineages; the initiation, timing, progress, results, and cost of BioNTech's research and development programs, including BioNTech's current and future preclinical studies and clinical trials, including statements regarding the expected timing of initiation, enrollment, and completion of studies or trials and related preparatory work and the availability of results, and the timing and outcome of applications for regulatory approvals and marketing authorizations; BioNTech's expectations regarding potential future commercialization in oncology, including goals regarding timing and indications, potential combination approaches, and estimated addressable patient populations; the targeted timing and number of additional potentially registrational trials, and the registrational potential of any trial BioNTech may initiate; discussions with regulatory agencies; BioNTech's expectations with respect to intellectual property; the impact of BioNTech's collaboration and licensing agreements; and BioNTech's ongoing activities with Biotheus. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

The forward-looking statements in this press release are based on BioNTech's current expectations and beliefs of future events and are neither promises nor guarantees. You should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech's control, and which could cause actual results to differ materially and adversely from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, projected data release timelines, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data, including the data discussed in this release, and including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; BioNTech's pricing and coverage negotiations regarding its COVID-19 vaccine with governmental authorities, private health insurers and other third-party payors; the future commercial demand and medical need for initial or booster doses of a COVID-19 vaccine; competition from other COVID-19 vaccines or related to BioNTech's other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response; the timing of and BioNTech's ability to obtain and maintain regulatory approval for its product candidates; the ability of BioNTech's COVID-19 vaccines to prevent COVID-19 caused by emerging virus variants; BioNTech's and its counterparties' ability to manage and source necessary energy resources; BioNTech's ability to identify research opportunities and discover and develop investigational medicines; the ability and willingness of BioNTech's third-party collaborators

to continue research and development activities relating to BioNTech's development candidates and investigational medicines; unforeseen safety issues and potential claims that are alleged to arise from the use of products and product candidates developed or manufactured by BioNTech; BioNTech's and its collaborators' ability to commercialize and market BioNTech's COVID-19 vaccine and, if approved, its product candidates; BioNTech's ability to manage its development and related expenses; regulatory developments in the United States and other countries; BioNTech's ability to effectively scale its production capabilities and manufacture its products and product candidates; risks relating to the global financial system and markets; and other factors not known to BioNTech at this time.

You should review the risks and uncertainties described under the heading "Risk Factors" in BioNTech's Report on Form 6-K for the period ended September 30, 2024 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC's website at www.sec.gov. These forward-looking statements speak only as of the date hereof. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise.

CONTACTS

Investor Relations
Michael Horowicz
Investors@biontech.de

Media Relations
Jasmina Alatovic
Media@biontech.de

Exhibit 99.2

43rd J.P. Morgan Healthcare Conference

Prof. Ugur Sahin, M.D.
CEO & Co-founder

14 January 2025
9:00 – 9:40 AM PST

BIONTECH

This Slide Presentation Includes Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: BioNTech's expected revenues and net profit/(loss), particularly for those figures that are derived from preliminary estimates provided by BioNTech's partners; the rate and degree of market acceptance of BioNTech's investigational medicines, if approved; the initiation, timing, progress, results, and cost of BioNTech's research and development programs, including BioNTech's current and future preclinical studies and clinical trials, including statements regarding the expected timing of initiation, enrollment, and completion of studies or trials and related preparatory work and the availability of results, and the timing and outcome of applications for regulatory approvals and marketing authorizations; BioNTech's expectations regarding potential future commercialization in oncology, including goals regarding timing and indications, potential combination approaches, and estimated addressable patient populations; the targeted timing and number of additional potentially registrational trials, and the registrational potential of any trial BioNTech may initiate; discussions with regulatory agencies; BioNTech's expectations with respect to intellectual property; BioNTech's acquisition of Biotheus, which is subject to customary closing conditions, including regulatory approvals; the impact of BioNTech's acquisition of Biotheus upon closing; collaboration and licensing agreements; and BioNTech's estimated cash balance. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

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Furthermore, certain statements contained in this presentation relate to or are based on studies, publications, surveys and other data obtained from third-party sources and BioNTech's own internal estimates and research. While BioNTech believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, any market data included in this presentation involves assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. While BioNTech believes its own internal research is reliable, such research has not been verified by any independent source. In addition, BioNTech is the owner of various trademarks, trade names and service marks that may appear in this presentation. Certain other trademarks, trade names and service marks appearing in this presentation are the property of third parties. Solely for convenience, the trademarks and trade names in this presentation may be referred to without the ® and TM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

A glossary of defined terms can be found at the end of the presentation.


Building a
Global Immunotherapy Powerhouse
Translating Science into Survival
BIONTECH

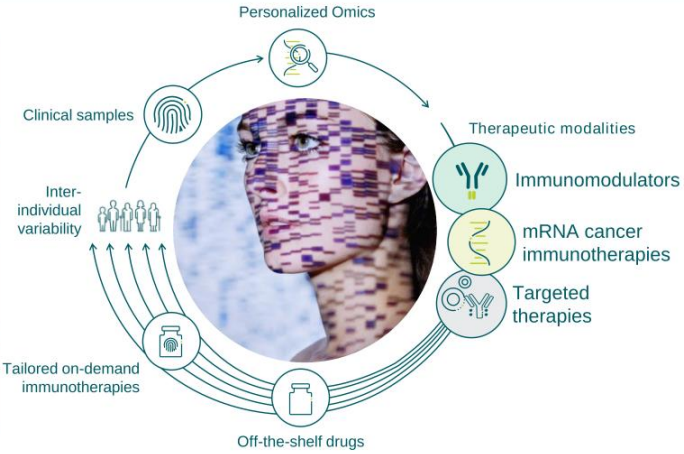
2024 Accomplishments Position Us for Success in 2025

Oncology Portfolio	Advanced oncology portfolio into late stage with 15 ongoing Phase 2 and Phase 3 trials
BNT327/PM8002[1]	Presented multiple datasets for BNT327[1] and announced pivotal trials targeting unmet needs in SCLC, TNBC, and NSCLC
Corporate Development	Strengthened position by planned Biotheus acquisition[2]: Securing global control of BNT327[1] and expanded pipeline and in-house immunotherapy capabilities
COVID-19[3] and Infectious Disease Vaccines	Maintained leading COVID-19[3] market share globally (>50%) underscoring competitive strength and progressed early-stage infectious disease pipeline
Cash Balance[4]	Strengthened balance sheet through strong financial performance, reinforcing long-term growth potential: **~€ 17.4 bn** total cash and cash equivalents plus security investments[4]

1. BNT327/PM8002 partnered with Biotheus. In this presentation, BNT327/PM8002 will further be referred to as "BNT327"; 2. Expected to close in Q1 2025, subject to satisfaction of customary closing conditions, including regulatory approvals; 3. Partnered with Pfizer; 4. Preliminary, unaudited figure; consists of cash, cash equivalents and security investments, as of December 31, 2024.

We Have Unique Capabilities to Build Tomorrow's Personalized Precision Medicines

- Deep genomics & immunology expertise to analyze patient data
- Individualized treatment platforms to address inter-individual variability
- AI-infused, digitally-integrated target & drug discovery and development
- Automated in-house manufacturing to serve patients on time and globally



Our Leading Scientific Capabilities are Fueled by AI to Pioneer Personalized Immunotherapies

Personalized immunotherapy

iNeST[1]: Personalized immunotherapy platform utilizing AI to create therapies unique to each patients' tumor

- 4 ongoing trials
- >450 patients treated[2]
- 18,000 neoantigens selected[2]

Computational extension of immunotherapy target space[3]

Semi-automated manufacturing capabilities for iNeST[1]

AI empowered bio-engineering

Development of novel DeepChain platform combining cutting-edge AI and bio-engineering

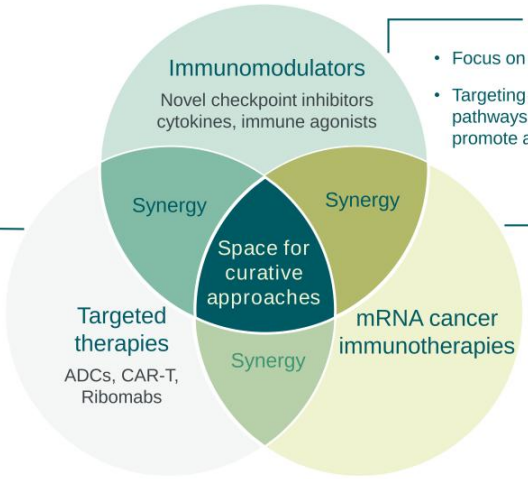
Optimization of mRNA design & structure

Automated dry-wet lab to enhance discovery capabilities

In-house supercomputing cluster is among worldwide top 100[4]

1. Partnered with Genentech, a member of the Roche Group. 2. From trials BNT122-01, GO39733, GO40558 and ML41081; 3. Castle et al. 2011 Cancer Res; 4."Top 500, The List", June 2023.

We are Uniquely Positioned to Combine Approaches to Transform Cancer Care



Immunomodulators

- Focus on the critical IO pathways
- Targeting different complementary pathways in cancer immunity cycle may promote a durable anti-tumor effect

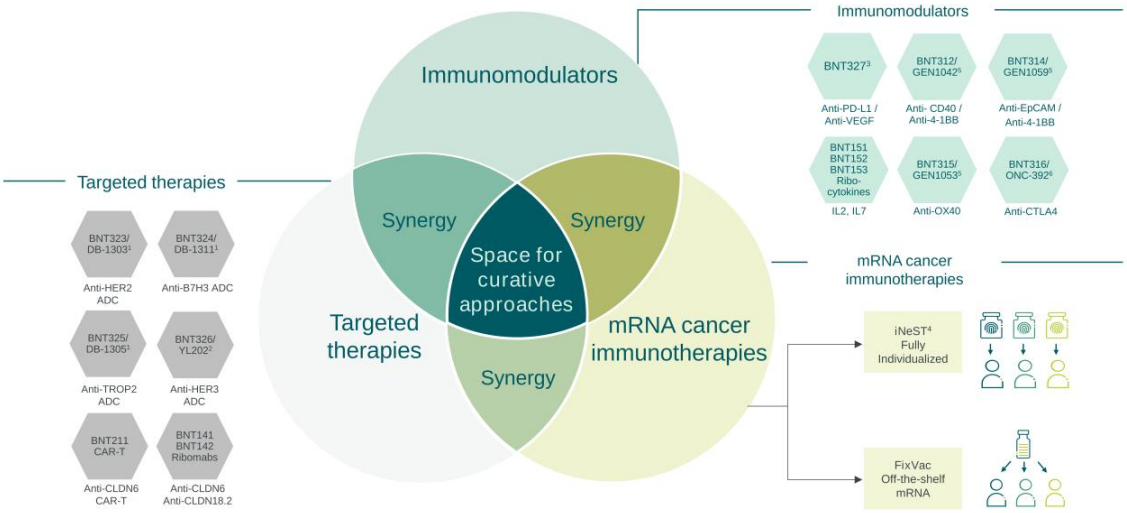
Targeted therapies

- Precise and potent modalities for fast onset tumor reduction
- ADC as potential "augmenters" of immunomodulators and mRNA cancer vaccines
- Focus on HER2, HER3, TROP2, B7H3 ADCs as combination partners

mRNA cancer immunotherapies

- Eliminate polyclonal residual disease with multi-antigen and individualized approaches
- Polyspecific activity by targeting multiple antigens at once
- Establish long-lasting immunological memory to prevent relapses

Our Unique Pipeline Has the Potential for a Curative Approach to Cancer



Partnered with 1. DualityBio; 2. MediLink; 3. BNT327/PM8002 partnered with Biotheus; 4. Genentech, a member of the Roche Group; 5. Genmab; 6. OncoC4

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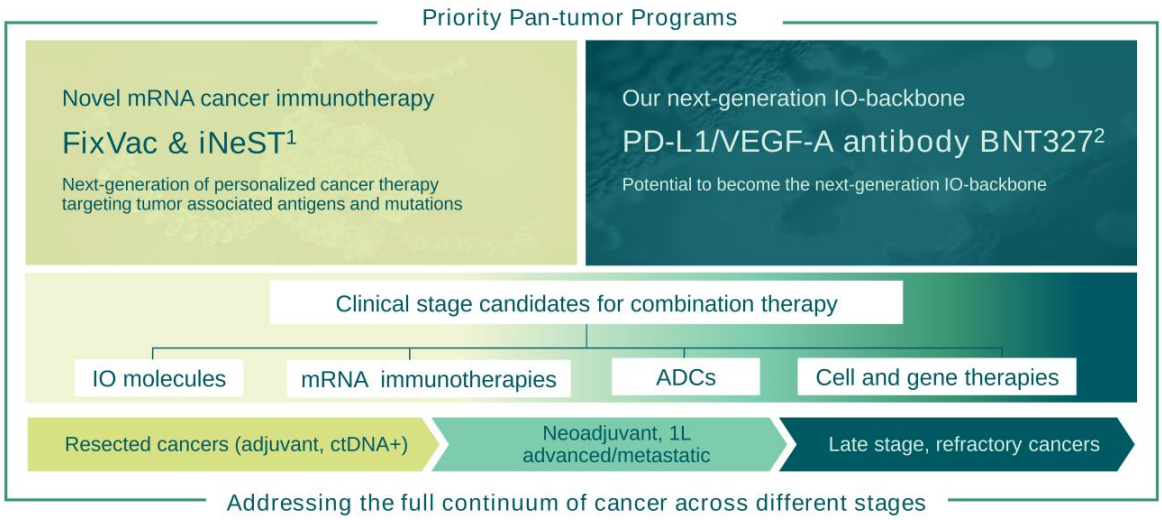
Our Priorities are Novel mRNA Cancer Immunotherapy and Next-Generation IO-Backbone



1. Partnered with Genentech, a member of the Roche Group; 2. BNT327/PM8002 partnered with Biotheus.

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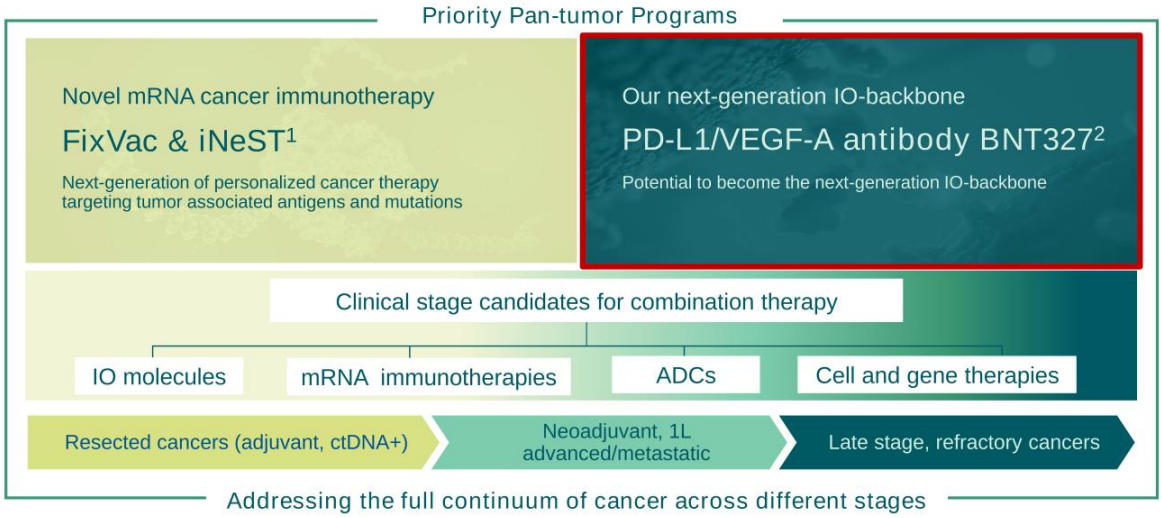
BNT327 as Potential Next-Generation IO-Backbone



1. Partnered with Genentech, a member of the Roche Group; 2. BNT327/PM8002 partnered with Biotheus.

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BNT327[1]: Data from 750 Patients Across Multiple Indications Highlight the Potential to Establish a New Standard of Care

>750 patients enrolled	Clinical activity across indications
10+ indications studied[2]	Including SCLC, NSCLC, TNBC, HCC, MPM and others
20 clinical trials ongoing or planned	Including studies in 1L or 2L with SoC CTx and novel combinations
3 global potentially registrational trials	Focus on 1L TNBC, SCLC, and NSCLC

1.BNT327/PM8002 partnered with Biotheus; 2. Indications included in Ph2a: NSCLC, mucosal melanoma, renal cell carcinoma, endometrial cancer, cervical cancer, platinum resistant ovarian cancer.

Differentiation of BNT327[1] by Binding to PD-L1 Allows Targeting to Tumor Site

	Cooperative effect linking PD-L1 and VEGF binding	Blocking of PD-L1 signaling	Neutralization of VEGF	TME Targeting by anti-PD-L1
BNT327[1] PD-L1/VEGF	YES	YES	YES	YES
PD-1/VEGF bispecifics	YES	YES	YES	NO

BNT327[1]

Dual targeting of TME

VEGF targeted PD-L1 inhibition

PD-L1 targeted VEGF neutralization

1. BNT327/PM8002 partnered with Biotheus; TME: Tumor Microenvironment

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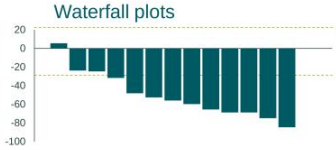
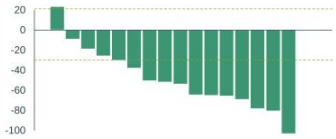
BNT327[1] May Drive Clinical Benefit Irrespective of PD-L1 Status

BNT327[1] + chemo in 1L TNBC, Y. Meng et al. Presented at ESMO 2024. Presentation 384MO

PD-L1 status	Waterfall plots	ORR Objective response rate
PD-L1 negative[2]		76.9%
PD-L1 low[2]		56.3%
PD-L1 high[2]		100.0%

BNT327[1] has the potential to become a backbone IO therapy for significant patient populations currently not addressed by existing IO therapies

1.BNT327/PM8002 partnered with Biotheus; 2. PD-L1 status in TNBC: negative= CPS<1; low= 1≤CPS<10; high= CPS≥10

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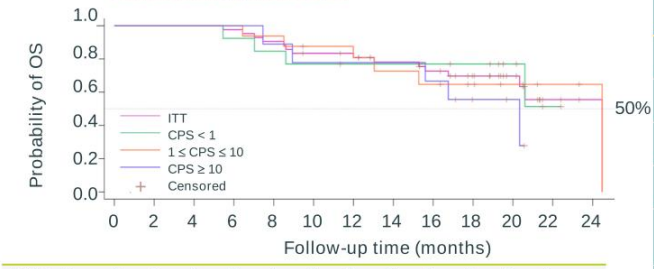
In 1L TNBC BNT327[1] with CTx Shows Encouraging Efficacy Irrespective of PD-L1 Status

Phase 1b/2 Study (NCT05918133): Interim overall survival (BNT327[1] + Nab-Paclitaxel):

Jiong Wu et al. Presented at SABCS 2024; Abstract number: SESS-3600 Poster number: PS3-08

Overall survival: Kaplan-Meier plot



CPS ≥ 10	9	9	9	9	8	7	7	7	6	3	2	0
1 ≤ CPS < 10	16	16	16	16	15	13	12	9	8	6	4	2	1
CPS < 1	13	13	13	12	11	10	9	9	8	7	4	1	0
ITT	42	42	42	41	38	34	32	29	26	20	12	3	1

Variable	ITT[2]	PD-L1 CPS<1	PD-L1 1≤CPS<10	PD-L1 CPS≥10
Population (n)	42	13	16	9
ORR %	73.8	76.9	56.3	100.0
DCR %	95.2	100.0	93.8	100.0
mPFS (mo)	13.5	18.1	14.0	10.8
12-mo OS rate %	80.8	76.9	80.8	77.8
15-mo OS rate %	78.1	76.9	72.7	77.8
18-mo OS rate %	69.7	76.9	64.6	55.6

BNT327[1] 18-mo OS rate of 69.7%. mOS not yet mature in ITT population.

1. BNT327/PM8002 partnered with Biotheus; 2. PD-L1 testing was not done in 4 patients (not shown): ORR: 75.0% and mPFS 14.0 months.

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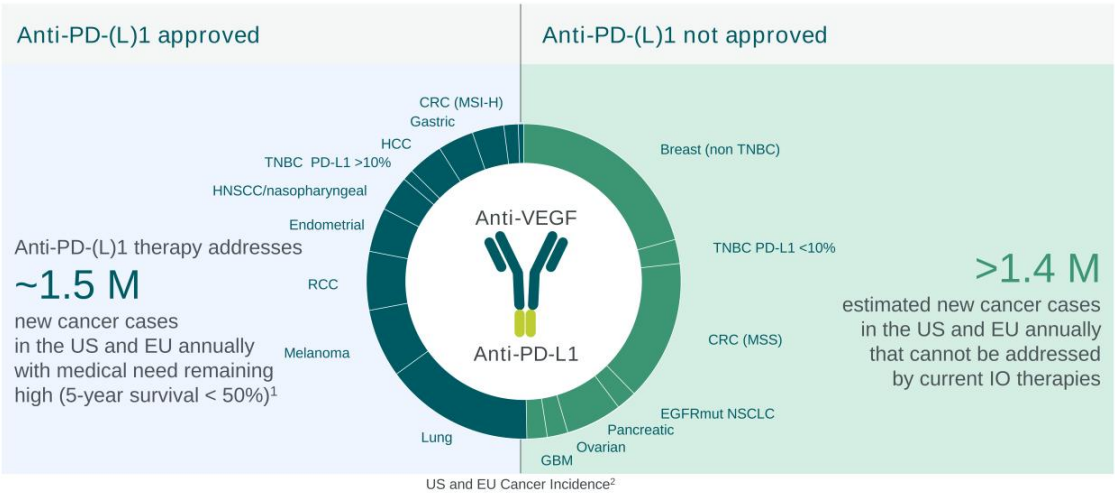
Broad Combination Strategy Across Indications Aiming to Establish Next-Generation IO-Backbone



1. NCI SEER https://training.seer.cancer.gov/index.html. 2.US incidence source: NIH and American Cancer Society data EU incidence source: European Cancer Information System

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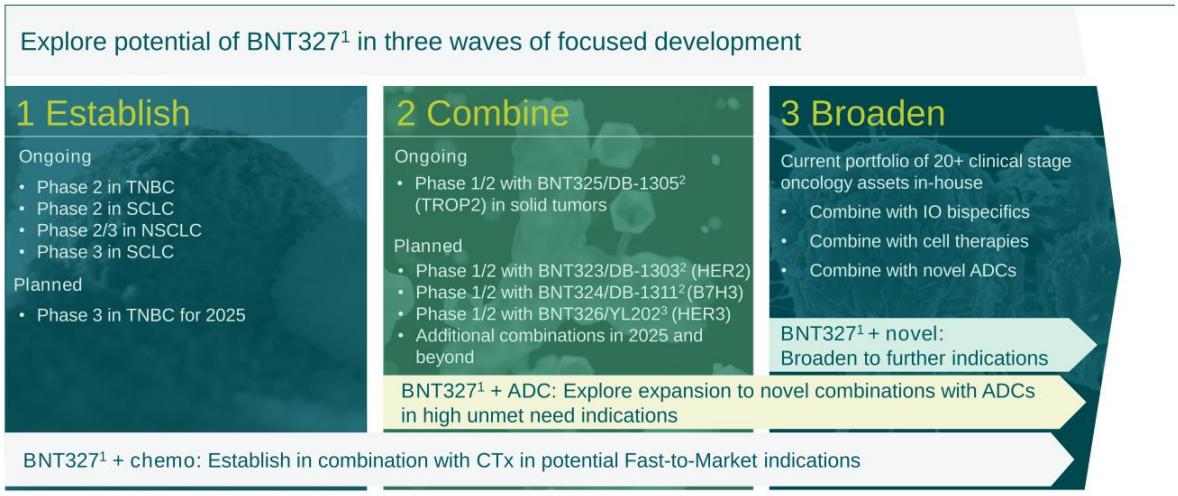
Accelerating Our Global Clinical Development Program for BNT327[1]



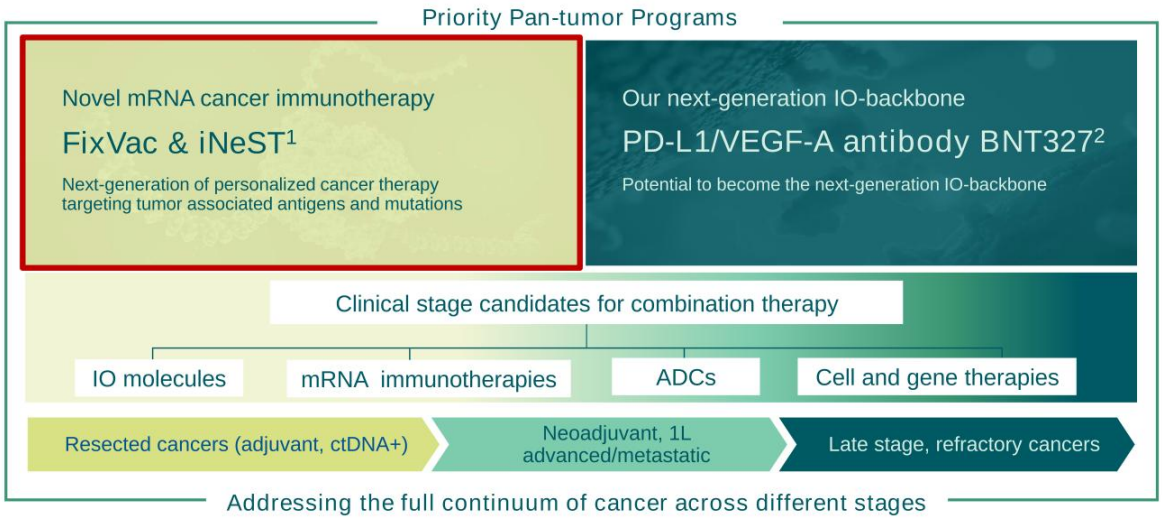
1. BNT327/PM8002 partnered with Biotheus; Partnered with: 2. DualityBio; 3. MediLink.

BNT327[1]: Data Readouts Expected in 2025

Indication	Target Population	Regimen	Phase	Region
SCLC	1L or 2L	+ chemo	2	Global
TNBC	1L or 2L	+ chemo	2	Global
Multiple solid tumors	Multiple lines	+ BNT325/DB-1305[2]	1/2	Global
SCLC	1L	+ chemo	2	China
SCLC	2L	+ chemo	2	China
MPM	1L	+ chemo	2	China

1. BNT327/PM8002 partnered with Biotheus; 2. Partnered with DualityBio.

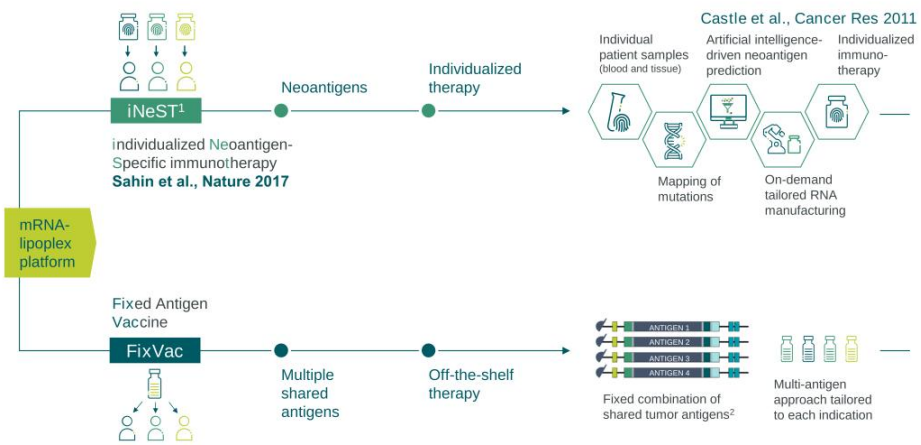
BNT327 as Potential Next-Generation IO-Backbone



1. Partnered with Genentech, a member of the Roche Group; 2. BNT327/PM8002 partnered with Biotheus.

BIONTECH

Leveraging Our Leadership in mRNA to Fully Exploit Cancer Immunotherapy Target Space with Two Approaches



Strong vaccine-induced ex vivo CD8+T cell responses across different cancer types[3]

1. Partnered with Genentech, a member of the Roche Group. 2. Antigens vary across programs; 3. T cell responses analyzed by ex vivo multimer staining analysis in blood.

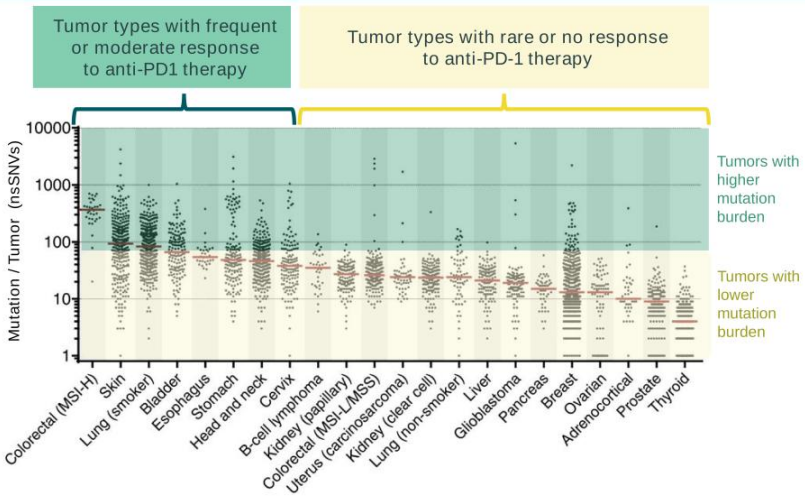
BIONTECH

T Cell Neoantigen Recognition is Critical for Effective Anti-PD-1 Therapy

Mechanism of anti-PD-1 immunotherapy

Anti-PD1 therapy is most effective in an environment where T cells are already primed and able to recognize tumor-specific neoantigens

Only 1-2% of mutations trigger spontaneous neoantigen-specific immune responses, making anti-PD-1 less effective in tumors with lower mutation burden



Vormehr et al., Curr Opin Immunol 2016

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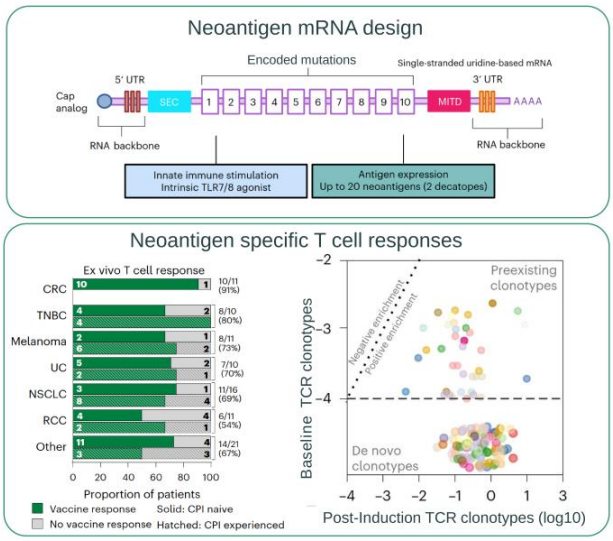
Autogene Cevumeran[1] Induces Neoantigen Specific T cells in a Broad Range of Cancers



First-in-human study (NCT03289962) in advanced and metastatic solid tumors

Autogene cevumeran[1] monotherapy (n=30)

Combination with atezolizumab (n=183)

- Well tolerated safety profile
- Strong neoantigen responses across broad spectrum of cancers
- Poly-epitopic, long-lasting neoantigen specific responses (CD4+, CD8+) in 71% of patients
- Expansion of pre-existing neoantigen T cells as well as induction of de novo T cell responses
- Immune therapy-Induced T cells were found in biopsies of post-treatment tumor lesions

Lopez et al. Autogene cevumuran with or without atezolizumab in advanced solid tumors, a phase1 trial. Nature Medicine, 2025

1. Partnered with Genentech, a member of the Roche Group

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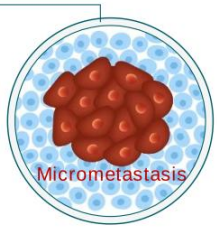
Evaluating Autogene Cevumeran[1] in the Adjuvant Treatment Setting for Cancers of High Unmet Need

Rationale for adjuvant setting

Low tumor mass with residual cancer cells

Resistance mechanisms, clonal heterogeneity and immune suppression not fully established



Healthier immune system and uncompromised T-cell function

Unmet medical need

Colorectal Cancer

Median DFS for ctDNA+ stage 2 (high risk) and stage 3 CRC post adjuvant chemotherapy: ≈ 11 months Reinacher-Schick et al., ASCO 2024	Randomized Phase 2 trial ongoing Data update expected in late 2025 / early 2026

Pancreatic Ductal Adenocarcinoma

69–75% relapse rate within 5 years after adjuvant therapy[2,3]	Phase 1 trial completed and published Randomized Phase 2 trial ongoing

Muscle-Invasive Urothelial Cancer (MIUC)

Significant number of patients relapse within 2 years after adjuvant nivolumab[4]	FPI in Dec 2024 Phase 2 study ongoing

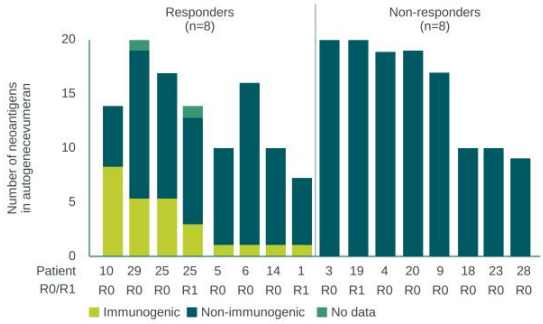
1. Partnered with Genentech, a member of the Roche Group; 2 Jones et al., Journal of American Medical Association (JAMA) Surgery 2019; 3. Conroy et al., JAMA Oncology 2022; 4. Bajorin et al., 2021 New England Journal of Medicine (NEJM).

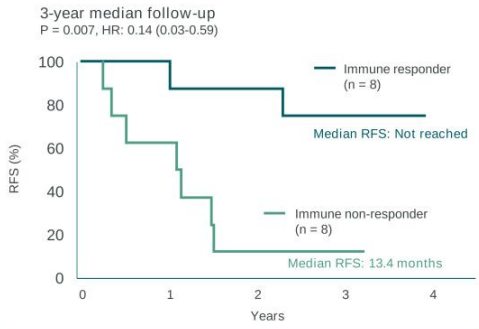
BIONTECH

Response to Autogene Cevumeran[1] Correlates with Delayed PDAC Recurrence

Phase 1, investigator-initiated trial in resectable PDAC: 3-year follow-up data

Balachandran et al., AACR 2024. #CT025 & Rojas et al., Nature 2023





At risk					
Responder	8	8	7	5	0
Non-responder	8	5	1	1	0

Half of all patients mounted neoantigen-specific de novo T cell responses against at least one vaccine neoantigen

1. Partnered with Genentech, a member of the Roche Group.

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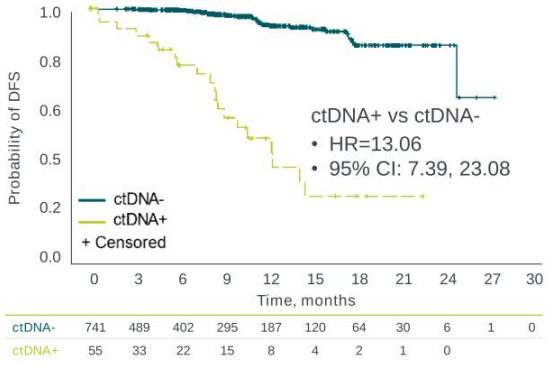
CRC Patients with Post-Surgery ctDNA Positivity Have Significantly Shorter DFS

DFS in patients who were ctDNA+ vs ctDNA- post surgery[1]
Reinacker-Schick. et al., ASCO 2024. Abstract #3526.



ctDNA-	741	489	402	295	187	120	64	30	6	1	0
ctDNA+	55	33	22	15	8	4	2	1	0		

BNT000-001: A multi-site epidemiological study of ctDNA status in Stage II/III CRC patients after resection and prior to adjuvant chemotherapy (NCT04813627)

Data cut-off March 15, 2024

Post-surgery ctDNA status can identify patients at high risk of disease recurrence (HR=13.06)

1. Patients who transferred to BNT122-01 (n=56) were excluded from this analysis.

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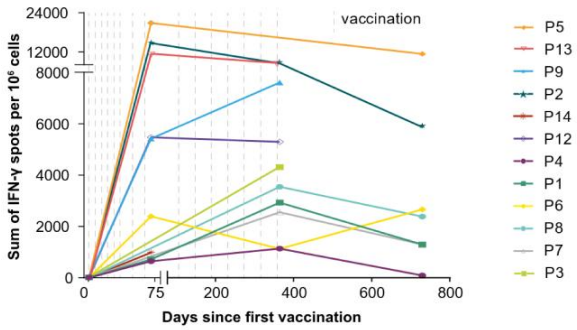
Vaccine-Induced T Cells are Long-Lived, Still Detected 1 Year After Last Vaccination with Autogene Cevumeran[1] in CRC Patients

Kinetics and persistence of T cell responses to immunotherapy-encoded neoantigens
Elez et. al., Biomarker sub-study results of Phase 2 trial (NCT04486378), ESMO-GI 2024.

Kinetics and durability of ex vivo T cell responses in individual patients (n=12)



Data cut-off March 15, 2024

- Autogene cevumeran[1] induced T cell responses in all patients
- Responses are polyepitopic; median of 3 vaccine-encoded neoantigens
- Almost all responses were detectable after 8 vaccinations
- All 12 patients included in the immunogenicity analysis were disease-free at data cut-off

1. Partnered with Genentech, a member of the Roche Group.

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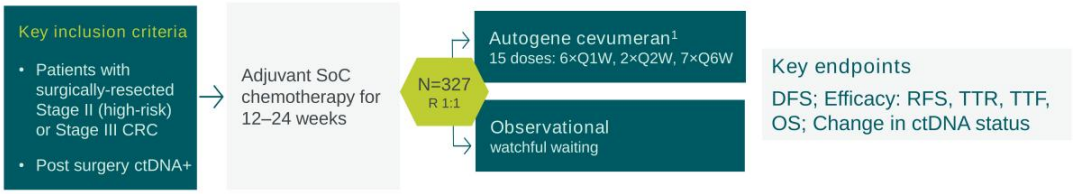
Ongoing Randomized Phase 2 Trial Evaluating Autogene Cevumeran in ctDNA+ CRC Patients

BNT122-01: Phase 2 multi-site, open-label, randomized, controlled trial (NCT04486378) vs. watchful waiting in adjuvant colorectal cancer



Key endpoints

DFS; Efficacy: RFS, TTR, TTF, OS; Change in ctDNA status

First data expected in late 2025 / early 2026

1. Partnered with Genentech, a member of the Roche Group.

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Multiple Clinical Trials Demonstrate Execution Across iNeST and FixVac Portfolios

Individualized immunotherapy: iNeST					FixVac		
Autogene cevumeran (BNT122/RO7198457)[1]					BNT111[2]	BNT113	BNT116
	Adjuvant		1L	R/R	R/R	1L	Multiple settings
MIUC Phase 2	CRC Phase 2	PDAC Phase 2	Melanoma Phase 2	Solid tumors Phase 1	Melanoma Phase 2	HPV16+ HNSCC Phase 2	NSCLC Phase 1 & 2
+ Nivolumab	Monotherapy	+ Atezolizumab + mFOLFIRINOX	+ Pembrolizumab	+ Atezolizumab	+ Cemiplimab	+ Pembrolizumab	Monotherapy, + Cemiplimab or CTx or aCTLA4
Recruitment ongoing	Recruitment ongoing Data presented from epi sub-study at ASCO 2024 and from biomarker sub-study at ESMO-GI 2024.	Recruitment ongoing Data presented from investigator-initiated Ph 1 trial at ASCO 2022 & AACR 2024 and published (Rojas et al., Nature 2023).	Enrollment completed Ph 1 data on prototype vaccine published (Sahin et al., Nature 2017). Analysis of Ph 2 PFS as primary endpoint will be based on events and defined when reporting results.	Enrollment completed Data presented at AACR 2020. Data published (Lopez et al., Nature Medicine 2025)	Enrollment completed Positive topline data announced July 2024 Data presented from Ph 1 at multiple conferences incl. SITC 2021 and published (Sahin et al., Nature 2020).	Recruitment ongoing Ph 2 data presented at multiple conferences incl. ESMO-IO 2022 Data from safety run-in of Ph 2 trial and Ph 1/2 IIT presented at ESMO 2024.	Recruitment ongoing in Ph 2 in 1L NSCLC[2] Ph 1 trial ongoing. Data presented at SITC 2023, AACR 2024, and SITC 2024.

1. Partnered with Genentech, a member of the Roche Group; 2. In collaboration with Regeneron.

Data expected in 2025 or 2026

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Our Priorities for 2025

mRNA Cancer Immunotherapy

» Expect multiple randomized Phase 2 data readouts

» Execute 7 ongoing Phase 2 trials and first novel combination trials

COVID-19 Vaccine[1] & ID

» Maintain global COVID-19 vaccine[1] market leadership

» Advance next-gen and combination offerings

» Multiple updates expected on ID pipeline

BNT327[2]

» Advance 3 global registration-enabling trials in potential fast-to-market indications

» Generate first BNT327[2]+ ADC combination data sets

Commercial Readiness in Oncology

» Advance BNT323/DB-1303[3] towards BLA submission

» Build targeted AI-enabled commercialization team in key markets

1. Partnered with Pfizer; 2. BNT327/PM8002 partnered with Biotheus; 3. Partnered with DualityBio.

Advancing Our Vision for Oncology:
A Once In a Generation Opportunity to Transform Medicine for Cancer Patients

2025

Execute on late-stage trials for BNT327[1] and our mRNA cancer immunotherapy portfolio

Continuation of our novel combination strategy

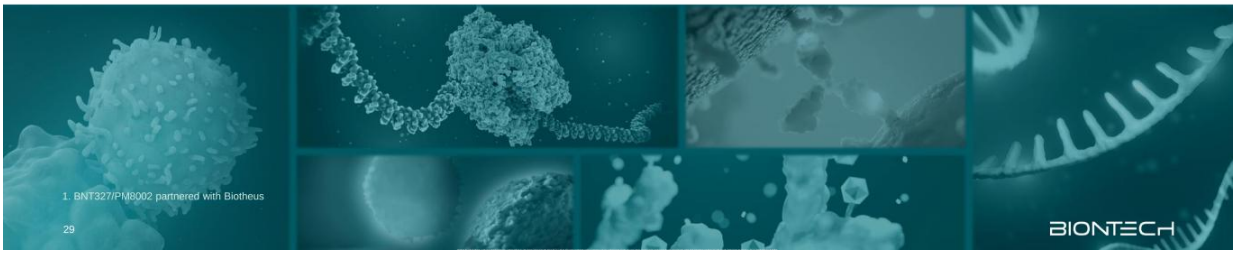
2026-2029

Prepare and execute launches of multiple oncology products across the world

2030

A diversified multi-product global immunotherapy powerhouse

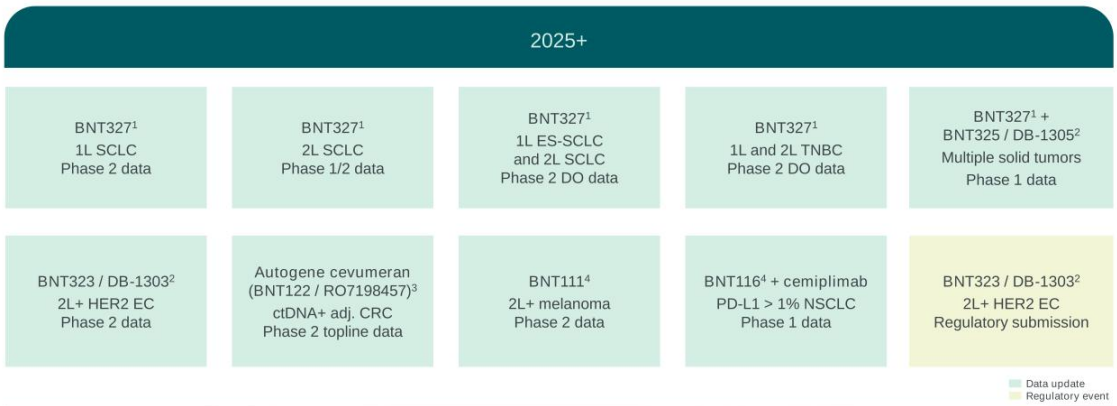
Turning Science into Survival



1. BNT327/PM8002 partnered with Biotheus

Thank you

Expected Potential Value Creating Milestones and Trials



Catalyst-rich period for later-stage pipeline to support company goal to achieve a diversified, cashflow-generating multi-product oncology portfolio by 2030

Partnered with: 1. Biotheus; 2. DualityBio; 3. Genentech, a member of Roche Group; 4. In collaboration with Regeneron.

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Glossary

n L	nth line	HPV	Human papilloma virus	PDAC	Pancreatic ductal adenocarcinoma
AACR	American Association for Cancer Research	HR	Hazard ratio / hormone receptor	PD-(L)1	Programmed cell death protein (ligand) 1
ADC	Antibody-drug conjugate	ID	Infectious disease	PFS	Progression-free survival
AI	Artificial intelligence	IFN	Interferon	QxW	Every x week(s)
ASCO	American Society of Clinical Oncology	IIT	Investigator initiated trial	RCC	Renal cell carcinoma
BLA	Biologics License Applications	IL-x	Interleukin x	RFS	Recurrence-free survival
CAR-T	Chimeric antigen receptor T cell	iNeST	Individualized NeoAntigen-Specific Therapy	R/R	Relapsed/refractory
CD-x	Cluster of differentiation	IO	Immuno-oncology	SABCS	San Antonio Breast Cancer Symposium
CLDN6	Claudin 6	ITT	Intention to treat	(ES)SCLC	(Extensive stage) small cell lung cancer
CPS	Combined positive score	MITD	Microtubule interacting and trafficking domain	SEC	Selenocysteinyl-tRNA
CPI	Checkpoint inhibitor	MIUC	Muscle-invasive urothelial carcinoma	SITC	Society of Immunotherapy of Cancer
CRC	Colorectal cancer	m	Median	SoC	Standard of care
ctDNA	Circulating tumor DNA	mo	Months	TCR	T-cell receptor
CTx	Chemotherapy	MPM	Malignant pleural mesothelioma	TLR7/8	Toll-like receptor 7/8
DCR	Disease control rate	mRNA	Messenger ribonucleic acid	TME	Tumor microenvironment
DFS	Disease-free survival	MSI-H(L)	High(low)-frequence microsatellite instability	TNBC	Triple-negative breast cancer
DO	Dose optimization	MSS	Microsatellite stability	TROP2	Trophoblast cell-surface antigen 2
EC	Endometrial cancer	NCT	National clinical trial	TTF	Time to treatment failure
EpCAM	Epithelial cell adhesion molecule	NIH	National Institutes of Health	TTR	Time to response
ESMO	European Society for Medical Oncology	NSCLC	Non-small cell lung cancer	UC	Urothelial cancer
GI	Gastrointestinal	nsSNV	Nonsynonymous somatic variants	UTR	Untranslated region
HCC	Hepatocellular carcinoma	ORR	Objective response rate	VEGF(R)	Vascular endothelial growth factor (receptor)
HER2 (or 3)	Human epidermal growth factor receptor 2 (or 3)	OS	Overall survival		
HNSCC	Head and neck squamous cell carcinoma	OX40	CD134		